IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	)Civil Action No. 05-00360 (KAJ))(consolidated)
THIS DOCUMENT RELATES TO:	)
[Cases Listed on Following Page]	)

INDIRECT PURCHASER PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' CONSOLIDATED MOTION TO DISMISS PLAINTIFFS' COMPLAINTS

REDACTED PUBLIC VERSION

LABATON SUCHAROW & RUDOFF LLP
Bernard Persky
Christopher J. McDonald
Kellie C. Safar
100 Park Avenue
New York, NY 10001

MILLER FAUCHER and CAFFERTY LLP
Bryan L. Clobes
William R. Kane
One Logan Square
18 & Cherry Streets, Suite 1700
Philadelphia, PA 19103
-and-
Patrick E. Cafferty
101 N. Main Street, Suite 450
Ann Arbor, MI 48101
-and-
Marvin A. Miller
Jennifer W. Sprengel
30 N. LaSalle St. Suite 3200
Chicago, IL 60602
Interim Co-Lead Counsel For End-Payor Plaintiffs

CHIMICLES & TIKELLIS LLP
Pamela S. Tikellis (#2172)
Robert J. Kriner, Jr. (#2546)
A. Zachary Naylor (#4439)
Robert R. Davis (#4536)
P.O. Box 1035
One Rodney Square
Wilmington, DE 19899
Tel: 302-656-2500
Fax: 302-656-9053
Liaison Counsel for End-Payor Plaintiffs

SPECTOR, ROSEMAN & KODROFF, P.C.
Jeffrey L. Kodroff
Theodore M. Lieverman
Simon B. Paris
1818 Market Street, Suite 2500
Philadelphia, PA 19103

HAGENS BERMAN SOBOL SHAPIRO LLP
Thomas M. Sobol
David S. Nalvin
Gregory H. Matthews
One Main Street, 4th Floor
Cambridge, MA 02142
-and-
Steve W. Berman
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Interim Co-Lead Counsel For End-Payor Plaintiffs

Dated: December 2, 2005

IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION	Civil Action No. 05-00360 (KAJ) (consolidated)
THIS DOCUMENT RELATES TO: PAINTERS' DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND and RICHARD G. WILDE, C.A. No. 05-360(KAJ) VISTA HEALTH PLAN, INC., C.A. No. 05-365 (KAJ) PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, C.A. No. 05-390 (KAJ) ALLIED SERVICES DIVISION WELFARE FUND and HECTOR VALDES, C.A. No. 05-394 (KAJ) DIANA KIM, C.A. No. 05-426 (KAJ) ELAINE M. PULLMAN, NEIL PERLMUTTER, HELENA PERLMUTTER and LULA RAMSEY, C.A. No. 05-450 (KAJ) PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND, C.A. No. 05-467 (KAJ) CINDY CRONIN, C.A. No. 05-482 (KAJ) CHARLES SHAIN and SANDRA KRONE, C.A. No. 05-475 (KAJ) LOCAL 28 SHEET METAL WORKERS, C.A. No. 05-516 (KAJ) ALBERTO LITTER, C.A. No. 05-695 (KAJ)	

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

MISCELLANEOUS

Indirect Purchaser Plaintiffs ("End-Payor Plaintiffs") hereby respond in opposition to Defendants' consolidated opening brief in support of their consolidated motion to dismiss Plaintiffs' complaints ("Defs. Br.").

I. NATURE AND STAGE OF THE PROCEEDING

Defendants would have this Court believe that the Generic Manufacturer Plaintiffs are the modern day equivalent of disgruntled buggy-whip manufacturers engaged in a misguided effort to prevent the automobile from making their products obsolete.[1] Throughout their motion, Defendants repeatedly mischaracterize this case as one in which they are being persecuted merely because they decided "to introduce new products and discontinue old ones." Defs. Br. at 1. But that is not what this case is about; no party is advocating that the judiciary insert itself to stem the tide of technological innovation or protect the interests of flat-footed competitors who cannot adapt to evolving economic conditions. To the contrary, this case involves standard fare in civil litigation and claims this Court is readily capable of resolving – allegations that monopolists are engaging in unlawful anticompetitive activity to perpetuate their market dominance.

Pursuant to a license granted by defendant Fournier, defendant Abbott manufactures and markets the "TriCor" brand of prescription cholesterol-lowering drug products. The active pharmaceutical ingredient in all TriCor products is fenofibrate. End-Payor Plaintiffs allege that Abbott and Fournier have implemented a scheme, the goal of which (in Fournier's own words) is to REDACTED This scheme abuses aspects of the complex health care delivery system and regulatory environment to deprive

[1] "Generic Manufacturer Plaintiffs" refers collectively to Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (together, "Teva") and Impax Laboratories, Inc. ("Impax"). "Direct Purchaser Plaintiffs" refers collectively to the plaintiffs in the "Walgreen Complaint," the "CVS Complaint" and the "Consolidated Direct Purchaser Complaint," as those terms are defined in footnote 1 of Defs. Br. "Plaintiffs" refers collectively to all plaintiffs in these consolidated proceedings.

doctors and consumers of an opportunity to choose less expensive generic fenofibrate formulations. Simply put, the Generic Manufacturer Plaintiffs have sought to introduce generic versions of Abbott's TriCor products and Defendants have affirmatively blocked such entry through unlawful anticompetitive means.

Broadly speaking, Defendants implemented a scheme to frustrate and nullify the effect of new applications for regulatory approval of generic versions of TriCor with a multifaceted approach. The scheme was designed to accomplish two overarching goals: (1) delaying generic entry, and (2) switching TriCor patients from one version of the drug (i.e., the version that is the subject of the generic challenge) to another version. Defendants accomplish the first goal by, *inter alia*, initiating frivolous patent infringement litigation against the would-be generic entrant. Under federal legislation known as the Hatch-Waxman Act, such litigation triggers a 30-month stay during which the U.S. Food and Drug Administration ("FDA") is statutorily precluded from giving final approval to a generic product that is the subject of a pending patent infringement suit. With the time bought by the 30-month stay, Defendants move to accomplish their second goal – forcing patients to migrate to a slightly different iteration of TriCor. Abbott has applied for and received regulatory approval to market a series of slightly different fenofibrate-containing products under the TriCor brand. It is undisputed that each new iteration of TriCor treats the same condition as did the prior version. However, and here is the key, it is impossible to substitute a generic version of TriCor for the new iteration. Abbott accomplishes this by ceasing to market its previous formulation and withdrawing the previous formulation from the marketplace. To ensure success, Abbott withdraws the previous formulation's product codes from databases used throughout the U.S. healthcare industry – databases used, *inter alia*, for purposes of identifying generic substitutes to brand-name drugs. Because the old formulation branded product is no longer marketed and no longer exists in

these databases, pharmacists cannot substitute a generic version of an older formulation for a prescription written for a new TriCor product. So even when a generic manufacturer wins in court, it is still blocked from the marketplace – and end-payors are deprived of the opportunity to purchase lower-priced generic versions of fenofibrate-containing products.

Thus, Defendants are not monopolists because their superior products allow them to maintain a dominant market share; rather, they are able to maintain their monopoly share because they are engaging in conduct that unlawfully stifles competition.

In response to Defendants' scheme, End-Payor Plaintiffs have brought a five-count Consolidated Class Action Complaint (the "End-Payor Complaint") seeking the following: injunctive relief under the federal antitrust laws (Count I); damages under the antitrust and/or consumer protection statutes of 23 states and the District of Columbia (commonly referred to collectively as the "Indirect Purchaser States") (Count II); restitution, disgorgement and constructive trust for unjust enrichment (Count III); violation of the Delaware Consumer Fraud Act, 6 Del. C. §§2511 *et seq.*, and particularly 6 Del. C. §§2513(a) (Claim IV), and; unfair and deceptive trade practices in violation of all 50 states and the District of Columbia (Count V). Defendants have moved to dismiss all claims in the End-Payor Complaint and all claims asserted in the other actions with which End-Payor Plaintiffs' action has been coordinated for pretrial purposes.[2]

II. SUMMARY OF ARGUMENT

1. With their TriCor product line, Defendants are monopolists in the market for prescription drugs containing the anti-cholesterol agent fenofibrate. Defendants have been able to maintain their monopoly position *not* because they have won the battle for

---

[2] "¶__" denotes references to paragraphs in the End-Payor Complaint.

consumer dollars over less worthy generic fenofibrate products, but rather because they have unlawfully prevented brand-versus-generic competition from occurring in the marketplace. Competing fenofibrate products that have obtained regulatory approval as generic substitutes for TriCor products cannot be *marketed* as generics because Defendants unlawfully have taken affirmative steps to prevent the Generic Manufacturer Plaintiffs from being able to do so. *See, e.g.*, ¶¶ 53-93. Defendants have thus engaged and continue to engage in conduct designed to "foreclose competition, gain a competitive advantage, or to destroy a competitor" (*United States v. Dentsply Int'l Inc.*, 399 F.3d 181, 186 (3d Cir. 2005) (quoting *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482-83 (1992))), which violates state and federal antitrust law, state consumer protection statutes and common law.

2. Defendants ignore two legal standards for assessing their conduct that are critical for viewing the factual allegations in the light most favorable to End-Payor Plaintiffs. First, as recently reaffirmed by the Third Circuit, "[b]ehavior that otherwise might comply with antitrust law *may be impermissibly exclusionary when practiced by a monopolist.*" *Dentsply*, 399 F.3d at 187 (emphasis added). Second, Defendants impermissibly seek to compartmentalize discrete factual allegations and to construe each in isolation to argue that each act involved no violation of the law. But the test to ascertain whether a defendant willfully acquired or maintained monopoly power focuses on the defendant's conduct *as a whole*, and not merely on individual elements. *See Strong v. BellSouth Telecomms., Inc.*, No. 93-0999, 1994 WL 1016699, at *3 (W.D. La. Jan. 24, 1994), *affd*, 137 F.3d 844 (5th Cir. 1998) (emphasis added) (citing *See Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)). While the End-Payor Complaint would survive scrutiny on a

dismissal motion even without benefit of these standards, their application confirms that End-Payor Plaintiffs have easily met their burden for pleading a claim on which relief can be granted.

3. Defendants have "gamed the system" by using the Hatch-Waxman Act to thwart the very public policy goals that Hatch-Waxman was designed to further. The End-Payor Complaint (incorporating by reference counterclaims asserted by Teva) alleges that Defendants have deceived the Patent and Trademark Office ("PTO") and engaged in sham patent infringement litigation. ¶¶ 81-85. Despite the claim that this was done to stall generic entry as part of their overall conspiracy to maintain their monopoly, Defendants argue that these allegations do not constitute "antitrust injury." But this is precisely the type of injury contemplated by the antitrust laws. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). *See also In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000) ("*Warfarin II*") (pharmaceutical company accused of engaging in anticompetitive conduct that impeded generic competition: "The excess amount paid by Coumadin users not only is inextricably intertwined with the injury DuPont aimed to inflict, the overcharge was the aim of DuPont's preclusive conduct. *It is difficult to imagine a more formidable demonstration of antitrust injury.*") (emphasis added; internal quotes omitted).

4. End-Payor Plaintiffs' state law claims are well-pleaded and survive Defendants' motion. Defendants argue that state antitrust law claims must be dismissed because the federal antitrust claims fail. Defendants are wrong about the federal claims, so they are wrong about the state claims. Defendants further seek dismissal of claims under consumer protection act statutes (Counts IV and V) because End-Payor Plaintiffs have purportedly failed to allege deception. But the End-Payor Complaint does allege that Defendants deceived the PTO and the FDA. ¶¶ 81-85. Moreover, the Delaware Consumer

Fraud Act, 6 Del. C. §2513 does not require that plaintiffs plead or prove individual reliance on a defendant's inequitable conduct. *See Stephenson v. Capano Dev., Inc.* 462 A.2d 1069, 1074 (Del. 1983). *See also Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 248 (D.Del. 2002) ("*Warfarin III*"), *aff'd*, 391 F.3d 516 (3d Cir. 2004) (plaintiffs' DCFA claims "do not rely on the conduct or reliance of individual consumers or [third-party payors]"). Likewise, statutes in other states do not require "deception."

III. STATEMENT OF FACTS

The End-Payor Complaint alleges a scheme that includes the following components: Defendants brought particular formulations of a TriCor fenofibrate products to market. ¶¶ 5(a), 49, 53, 67. When Defendants learned that generic competitors sought to market lower-cost bioequivalent generic fenofibrate products, Defendants engaged in a range of practices — including patent infringement suits that imposed a 30-month stays of FDA approval under the Hatch Waxman Act — that delayed the launch of competitive generic products until after a new formulation of TriCor could launched. ¶¶ 5(b), 52, 61-71. End-Payor Plaintiffs and other plaintiffs also allege that some or all of the patent actions were "shams" pursued solely for purposes of the delay they imposed under the Hatch-Waxman Act. *See* ¶¶ 8, 81-85.

While the delay tactics blocked competitive generic drugs from the market, Defendants exploited their monopoly to charge supra-competitive prices for TriCor products. Those prices are far higher than the prices generic competitors would charge if they were able to sell their bioequivalent versions of TriCor products. ¶¶ 5(c), 94-97.

Once market entry by competitive generic drug products appeared imminent, Defendants began selling a *new* formulation TriCor product. The new TriCor product involved minor variations in the fenofibrate formulations solely for the purpose of avoiding generic substitution, but was the same medicine, used for the same indications, as the prior formulation.

Defendants took affirmative steps to convert customers from the existing formulation to the new formulation before the competitive generic products became available for sale. ¶¶ 5(d), 53-55, 72-74.

Despite Defendants' efforts to convert all patients or doctors from the older formulations to the newer formulations, some of them would inevitably resist the switch and then gravitate to generic versions once they became available. To increase their likelihood of success, Defendants took affirmative steps to deprive patients and physicians of a choice, thus effectively eliminating the generic market for the prior formulation before the competitive generic versions were available to the public. For example, in 2002, Defendants removed its brand reference for TriCor capsules from the National Drug Data File® ("NDDF"), so that the branded drug code reference no longer exists for purposes of generic substitution laws or for purposes of health care providers' pharmaceutical benefit programs. In 2005, Defendants repeated this maneuver with its market shift to new tablet formulations. ¶¶ 5(e), 54-59, 75-77.

As a result of this scheme, once a generic manufacturer is able to start selling a product that is bioequivalent to a TriCor formulation — and therefore could be substituted by a pharmacist for the branded product — the market for that product was switched to the new product. Because the would-be generic formulation is bioequivalent only to a prior brand formulation, pharmacists and others cannot legally substitute the product for the new TriCor product, even though the products are indicated for the same uses. The product switch and the withdrawal of the NDDF code effectively eliminated generic competition that otherwise would have arisen. If Defendants had simply launched their new products, without affirmatively destroying the market for the prior products, consumers would benefit from the existence of competition in sales of fenofibrate products. Instead, because Defendants have improperly staved off generic competition and could potentially continue to do so indefinitely, Plaintiffs and

members of the Class have been forced to pay supra-competitive prices for and are deprived of lower-priced choices among fenofibrate products.

IV. ARGUMENT

A. Plaintiffs Have Sufficiently Alleged A Violation Of Section 2 Of The Sherman Act And Analogous State Statutes.

Rather than construe the several complaints filed in the light most favorable to Plaintiffs, Defendants' motion to dismiss erroneously labels Plaintiffs' claims as "Product Introduction" claims and attempts to recast Plaintiffs' claims as an attack on "the right to introduce new TriCor formulations and to discontinue the old TriCor formulations." Defs. Br. at 1; *see also id.* at 9-11. Not so.[3] While the antitrust laws do favor aggressive competition on the merits, even for a monopolist, they also impose limits on the affirmative steps a monopolist can take to smother competition.[4]

A violation of Section 2 consists of two elements: "(1) possession of monopoly power and (2) '... maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" *Dentsply*, 399 F.3d at 186 (quoting *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 480 (1992)). "To

---

[3] For example, the End-Payor Plaintiffs unambiguously allege that: "Plaintiffs *do not* challenge Abbott's and Fournier's right or ability to apply to the FDA for approval of new fenofibrate formulations. Instead, Plaintiffs' challenge Abbott's and Fournier's affirmative, anticompetitive conduct to destroy the market for existing fenofibrate formulations, and thereby preclude generic competition." ¶ 5 (emphasis added).

[4] Defendants also fail to grasp the concept that Plaintiffs' antitrust claims are not subject to a pleading standard any more rigorous than the "short and plain statement of the claim showing that the pleader is entitled for relief" pursuant to Fed. R. Civ. P. 8(a). *See, e.g., Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002) ("Rule 8(a)'s simplified pleading standard applies to all civil actions, with limited exceptions."); *Twombly v. Bell Atlantic Corp. et al.*, 425 F.3d 99, 108 (2d Cir. 2005) ("We have consistently rejected the argument – put forward by successive generations of lawyers representing clients defending against civil antitrust claims – that antitrust complaints merit a more rigorous pleading standard.").

run afoul of Section 2, a defendant must be guilty of illegal conduct 'to foreclose competition, gain a competitive advantage, or to destroy a competitor.'" *Id.* (quoting *Eastman Kodak*, 504 U.S. at 482-83). The Third Circuit recently reaffirmed that "[b]ehavior that otherwise might comply with antitrust law *may be impermissibly exclusionary when practiced by a monopolist.*" *Dentsply*, 399 F.3d at 187 (emphasis added).

> As we said in *LePage's, Inc. v. 3M*, 324 F.3d 141, 151-52 (3d Cir. 2003), "a monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior." 3 Areeda & Turner, Antitrust Law ¶ 813, at 300-02 (1978).

Id.

As the court in *Caldera, Inc. v. Microsoft Corp.*, 72 F. Supp. 2d 1295 (D. Utah 1999) explained:

> Perhaps the clearest way to explain what a monopolist may legally do is to say that the monopolist may engage in all of the same procompetitive activities that allowed it to become a legal monopolist in the first place. These would include building a better or less expensive product, engaging in better public relations, employing effective (and honest) advertising campaigns, and developing aggressive and effective marketing techniques. If these activities result in even more market share, and drive competitors out of the market, the monopolist is nevertheless fully entitled to such expansion, and its conduct is not a violation of the Sherman Act. Conversely, a *monopolist may not engage in any activities other than those that are procompetitive, as generally described above.*

Id. at 1306 (*emphasis* added). "Unlawful maintenance of a monopoly is demonstrated by proof that a defendant has engaged in anti-competitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power." *Dentsply*, 399 F.3d at 187

(citing *United States v. Microsoft*, 253 F.3d 34, 79 (D.C. Cir. 2001); 3 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law, ¶ 651c at 78 (1996)).

In this case, Plaintiffs' allegations demonstrate that Defendants violated Section 2 (and analogous state laws) because they wielded their power as monopolists to preclude the marketing of generic fenofibrate products that otherwise would have eroded their monopoly through price competition. Thus, it is Defendants' associated conduct in precluding the introduction of lower-priced, generic fenofibrate formulations that forms the basis of End-Payor Plaintiffs' monopolization claims.[5]

1. Defendants Have Monopoly Power In The Market For Fenofibrate Products.

"The concept of monopoly is distinct from monopoly power, which has been defined as the ability "to control prices or exclude competition." *Dentsply*, 399 F.3d at 187 (quoting *U.S. v. Grinnell Corp.*, 384 U.S. 563, 571 (1966)). The existence of monopoly power can be inferred from a predominant share of the market. *Id.* ("Absent other pertinent factors, a share significantly larger than 55% has been required to establish prima facie market power.").

---

[5] Defendants' reliance on in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979) and *Transamerica Computer Co. v. IBM*, 698 F.2d 1377, 1383 (9th Cir. 1983) is misplaced. Defendants' quote *Berkey Photo* that "any firm, even a monopolist, may generally bring its products to market whenever and however it chooses" (Defs. Br. at 14 quoting *Berkey Photo*, 603 F.2d at 286), but they omit the footnote on that quote, which reads:

> This is not to say, of course, that new product introductions are Ipso facto immune from antitrust scrutiny, and we do not agree with Kodak's argument that they are, *See, e. g., Sargent-Welch Scientific Co. v. Ventron Corp.*, 567 F.2d 701 (7th Cir. 1977), *Cert. denied*, 439 U.S. 822, 99 S.Ct. 87, 58 L.Ed.2d 113 (1978) (use of power over old product to promote sale of new); *in all such cases, however, it is not the product introduction itself, but some associated conduct, that supplies the violation.*

Berkey Photo, 603 F.2d at 286 n.30 (emphasis added). In *Transamerica*, the trial court found that IBM's design change *did* unreasonably restrict competition, but that plaintiff had failed to prove IBM was a monopolist or to prove an antitrust injury. 698 F.2d at 1383.

Defendants here do not dispute Plaintiffs' allegations that Defendants have monopoly power in the market for fenofibrate products. *See* ¶ 24 ("At all relevant times, Defendants' market share in the relevant product and geographic markets was [] between 95% and 100%.").

2. End-Payor Plaintiffs Have Alleged That Defendants Engaged In Illegal Conduct To Destroy Competition.

As stated by the court in *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979), relied upon by Defendants, "[t]he mere possession of monopoly power does not Ipso facto condemn a market participant. But, to avoid the proscription of § 2, the firm must refrain at all times from conduct directed at smothering competition." *Id.* at 275. "[A] firm with a legitimately achieved monopoly may not wield the resulting power to tighten its hold on the market." *Id.* Plaintiffs here have unambiguously alleged that Defendants are monopolists engaged in an anticompetitive scheme that included several interrelated components designed to smother competition. *See, e.g.*, ¶ 5 (summarizing allegations).[6]

Defendants' motion to dismiss erroneously breaks down the alleged scheme into individual components (at least the ones they choose to address), which they then construe standing alone to constitute lawful behavior. Defs. Br. at 8-17. When called upon to scrutinize a defendant's conduct and ascertain whether it willfully acquired or maintained monopoly power, however, courts should focus on the defendant's conduct as a whole, and not merely on individual elements. *Strong*, 1994 WL 1016699, at *3 (citing *Cont'l Ore Co. v. Union Carbide*

---

[6] End-Payor Plaintiffs and other plaintiffs also allege that Defendants pursued "sham" patent actions. *See* ¶¶ 8, 81-85; *infra* at pp. 20-22. The unlawful monopolization alleged in the End-Payor Complaint does not depend on these allegations, although they certainly reinforce the alleged scheme. *See* ¶ 7 ("Abbott's and Fournier's scheme unreasonably restrains competition even if their patent infringement actions are deemed lawful petitioning activity."); *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) ("Intellectual property rights do not confer a privilege to violate the antitrust laws.") (citation omitted).

& *Carbon Corp.*, 370 U.S. 690, 699 (1962) ("Plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.... [T]he character and effects of a [violation] are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.") (citation omitted). Applying this approach, the court in *Strong* stated that:

> While the defendant has certainly refuted, one by one, the plaintiffs' distinct allegations, we conclude that genuine issues of material fact exist, at a minimum, as to whether the defendant's conduct, even if lawful when separated into distinct categories, amounted to anticompetitive behavior by foreclosing or destroying competition. As was stated by the Supreme Court in *United States v. Griffin*, "[t]he anti-trust laws are as much violated by the prevention of competition as by its destruction. It follows a fortiori that the use of monopoly power, however, lawfully acquired, to foreclose competition, to gain a competitive advantage, or destroy a competitor, is unlawful." 334 U.S. 100, 68 S.Ct. 941, 92 L.Ed. 1236 (1947).

Strong, 1994 WL 1016699, at *3. *Accord Aspen Highlands Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1522 (10th Cir. 1984) ("Plaintiff's evidence should be viewed as a whole. Each of the 'six things' viewed in isolation need not be supported by sufficient evidence to amount to a § 2 violation. It is enough that taken together they are sufficient to prove the monopolization claim."), *aff'd*, 472 U.S. 585 (1985); *Caldera*, 72 F. Supp. 2d at 1309 ("[T]o allow defendant to carve plaintiff's complaint into seven discrete claims that plaintiff never intended to allege as independent claims not only appears to offend the purpose behind § 2, but also turns basic civil procedure principles on their head."). *See also In re Warfarin Sodium Antitrust Litig.*, No. 98-1232-SLR, 1998 WL 883469, at *11 (D. Del. Dec. 7, 1998) (holding that component parts of defendant's alleged conduct "could form part of an unlawful, multifaceted effort to hinder competition" and that the "combined effect of

defendant's conduct could harm competition"), *rev'd on other grounds*, *Warfarin II*, 214 F.3d 395.

Accordingly, in order to construe the End-Payor Complaint in the light most favorable to End-Payor Plaintiffs, the Court must reject Defendants' effort to isolate various components of the monopolization scheme. Even if each component might, standing alone, be construed as lawful behavior, that does not transform the allegations construed as a whole from demonstrating anticompetitive behavior by a monopolist to foreclose or destroy competition. *See Dentsply*, 399 F.3d at 186-87.

Indeed, for these same reasons, the entirety of Section V of Defendants' Brief, attacking Plaintiffs' "overall scheme" allegations, must be rejected out-of-hand. Defendants maintain that the component factual allegations are non-actionable when viewed individually and, thus, they must be non-actionable when viewed collectively. As explained above, that reasoning is precisely the opposite of what the law requires, and it completely ignores the fact that Defendants are alleged to have engaged in conduct that is independently unlawful.

(a) Defendants' Conduct Intentionally Subverted The Hatch-Waxman Act And Precluded The Introduction Of Generic Fenofibrate Products.

Even when addressing certain individual components of the scheme, Defendants mischaracterize or ignore the purpose and effect of their conduct on the market for fenofibrate products. Defendants incorrectly assert that they have not prevented "anyone from bringing a saleable product to the market," Defs. Br. at 11 (footnote omitted), while ignoring the key allegations that their conduct *has* completely foreclosed the ability of Teva, Impax and other generic manufacturers to bring *generic* products to the market. This distinction is critical because it has enabled Defendants to maintain a monopoly in the market for fenofibrate products.

Congress passed the Hatch-Waxman Act "to increase competition in the drug industry by facilitating the approval of generic copies of drugs." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (citation omitted). "Congress expected that competition 'to make available more low cost generic drugs.'" *Id.* (citing H.R.Rep. No. 98-857, pt. 1, at 14 (1984)). *See also Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) ("Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.") (quoting *In re Barr Lab., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). The Hatch-Waxman Act established the Abbreviated New Drug Application ("ANDA") approval process "which allows low-priced generic versions of previously approved innovator drugs to be approved and brought to market on an expedited basis." *Mylan Pharm., Inc. v. Thompson*, 207 F. Supp. 2d 476, 480 (N.D.W.Va. 2001). Under the Hatch-Waxman Act, generic drug makers are permitted to file an ANDA that incorporates data that the "pioneer" manufacturer has already submitted to the FDA regarding the pioneer drug's safety and efficacy. "In order to obtain FDA approval, the ANDA must demonstrate, among other things, that the generic drug is 'bioequivalent' to the pioneer drug." *Mylan v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000).

When generic drugs are available, they can usually be substituted by a pharmacists when filling prescriptions written for the branded drugs to which they are equivalent. *See* ¶ 94. Indeed, many states require such generic substitution.[7] A 1998 study conducted by the

---

[7] Delaware, for example, allows but does not require generic substitution. *See* 24 Del. Code § 2553(b) ("when a pharmacist receives a prescription for a brand or trade name drug product, the pharmacist may dispense a therapeutically equivalent drug product" subject to notice requirements, including informing the patient "that a generic drug has been dispensed which results in a monetary savings for the patient"). Other states are more aggressive and *require* generic substitution as the "default" in dispensing prescription drugs. New York's Education Law § 6816-a, for example, provides that "[a] pharmacist *shall* substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded [unless, *inter alia*, *(continued . . .)*

Congressional Budget Office ("CBO") concluded that the purchase of generic drugs saves consumers and third party payors between $8-10 billion in a single year.[8]

While Defendants have seized upon every opportunity provided by the Hatch-Waxman Act to *stall* generic competition — *i.e.*, multiple patent listings and prompt patent infringement lawsuits in response to Paragraph IV ANDAs (to invoke a 30-month stay of the FDA's authority to approve the ANDAs) — they proceeded to undermine the entire process by intentionally foreclosing the availability of generic drugs at its conclusion. Defendants' conduct precluded pharmacists' ability (and in most cases, legal obligation) to substitute a generic drug for a TriCor prescription, thereby permitting Defendants to maintain a monopoly. *See* ¶ 88 ("By withdrawing TriCor® capsules from the NDDF and ensuring that a code reference for the branded drug no longer exists for purposes of the U.S. Healthcare system, a prescription for TriCor® capsules *cannot be filled by the pharmacist at all, not even with a bioequivalent substitute marketed by Teva.* Similarly, an insured consumer attempting to fill a prescription for TriCor® capsules will not be able to do so, and will not have the option of substituting a generic version for a lower co-payment.") (emphasis in original).

(. . . continued)

prescription indicates "dispense as written" or similar language]" (emphasis added). *See also* Mich. Comp. Laws § 333.17755(2) ("If a pharmacist dispenses a generically equivalent drug product, *the pharmacist shall pass on the savings in cost to the purchaser or to the third party payment source if the prescription purchase is covered by a third party pay contract . . . .*") (emphasis added).

[8]June E. O'Neil, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry (1998)

http://www.cbo.gov/showdoc.cfm?index=655&sequence=0 (last visited November 29, 2005).

(b) Generic Formulations Can Be Just As Effective As Next Generation TriCor Formulations At A Fraction Of The Price.

Defendants tout the "enhanced" features of the new TriCor products and seek to impose upon Plaintiffs the burden of proving that the new TriCor products were "'absolutely no better' than the prior version." Defs. Br. at 12-13.[9] Even if, contrary to the allegations in the End-Payor Complaint, their asserted improvements to TriCor were genuine, Defendants do not dispute that, as Plaintiffs allege, generic versions of the initial TriCor formulations *can be just as therapeutically effective as the new products* by, for example, taking an earlier generation capsule or tablet with food.[10] The scheme made it impossible for patients satisfied with initial formulations of TriCor to obtain a generic versions at lower prices. *See* ¶¶ 88-89. Because of Defendants' anticompetitive activities, the overwhelming majority of patients were switched to the newer versions of TriCor *whether or not* they desired such a switch. *Compare Berkey Photo*, 603 F.3d at 287 ("If a monopolist's products gain acceptance in the market . . . it is of no importance that a judge or jury may later regard them as inferior, *so long as that success was not based on any form of coercion.* ... Unless consumers desired to use the 110 camera for its own

---

[9] FDA approval of new TriCor formulations does not signify that the new formulations are "better" than previous formulations. Before marketing a new drug in the United States a manufacturer must obtain the approval of the FDA contingent upon clinical (*i.e.*, human) tests showing that the drug is safe and effective. *See* 21 U.S.C. § 355(a), (d). Under this standard, the FDA approval demonstrates only that the drug is more effective than a placebo, not comparable drugs. *See* ¶ 3.

[10] *See* ¶ 93 ("Abbott's and Fournier's own data, however, show that two-thirds of patients using TriCor® tablets take the medicine with food in any event. The bioavailability of the original tablets, when taken with food, is equivalent to the bioavailability of the new tablets, which means that those patients who took the original tablets with food derive no significant medical benefit from the replacement formulation that they did not already obtain from the original tablets. For the same reasons, Abbott's and Fournier's replacement TriCor® tablets provide no significant medical benefit for the majority of patients taking fenofibrate that those patients would not also obtain by taking generic fenofibrate tablets. In other words, the majority of patients on fenofibrate are just as well off with the prior formulation — whether brand or generic — but it is unavailable to them as a generic. On information an belief, all patients using fenofribrate products also eat food.").

attractive qualities, they were not compelled to purchase Kodacolor II *especially since Kodak did not remove any other films from the market when it introduced the new one.*") (emphasis added).

(c) Federal And State Governments Have Promoted The Production Of Generic Drugs And Their Substitution For Branded Drugs.

Defendants' suggestion that it is improper for Teva and Impax to "free-ride on the TriCor brand" (Defs. Br. at 15) is specious because, as addressed above, it was Congress (through the Hatch-Waxman Act) and the states (through the enactment of generic substitution laws) that have encouraged the production of generic drugs and allowed or required their substitution for prescriptions written for brand-name drugs. Although Defendants have greatly benefited from the Hatch-Waxman regime with their monopoly of the fenofibrate product market, *see, e.g.*, ¶ 1 (TriCor totaled $779 million in 2004), their anticompetitive conduct has unlawfully extended that monopoly. While "Congress sought to get generic drugs into the hands of patients at reasonable prices – fast," *In re Barr Lab., Inc.*, 930 F.2d at 76, Defendants' scheme has precluded generic fenofibrate products *altogether*.[11]

Accordingly, End-Payor Plaintiffs have properly alleged that Teva and Impax were foreclosed by the conduct of a monopolist from marketing generic fenofibrate products. Defendants' contention that generic manufacturers should "promote and sell their own product" (Defs. Br. at 17) — which is at odds with the very existence of generic drugs and the

---

[11] This is a sharp contrast from *Medtronic Minimed Inc. v. Smiths Med. MD Inc.*, 371 F. Supp. 2d 578 (D. Del. 2005), relied upon by Defendants, where this Court noted that evidence did not support the contention that "the change in the connection system employed by MiniMed, in itself and without regard to the '695 patent, foreclosed the market in any meaningful way." *Id.* at 587.

substitution laws that favor them — cannot serve as justification for intentionally smothering generic competition.

(d) The First Amendment Does Not Preclude Consideration Of Defendants' Withdrawal Of TriCor Codes From The NDDF As Part Of The Scheme.

Finally, Defendants' claim to a First Amendment right to notify the NDDF of the discontinuation of its earlier formulations is a "red herring." Defs. Br. at 16-17. Plaintiffs do not suggest that "truthful commercial speech" should be prohibited, but rather, the fact of the NDDF code withdrawal should be considered as a component of the overall anticompetitive scheme.[12] "First Amendment rights are not immunized from regulation when they are used as an integral part of conduct which violates a valid statute." *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 514 (1972) (citation omitted). "If the end result is unlawful, it matters not that the means used in violation may be lawful." *Id.* at 515. As Judge Posner observed with respect to petitioning the government (which the NDDF is not, ¶ 98), the *Noerr-Pennington* doctrine cannot be treated "as a rule of evidence that forbids the introduction of evidence . . . relating to efforts to obtain governmental protection" to show an antitrust violation. *In re Brand-Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 789 (7th Cir. 1999); *see also In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 645 (E.D. Mich. 2000), *aff'd*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 125 S.Ct. 307 (2004).("State Law Plaintiffs

---

[12] *See* ¶ 58 ("Because Abbott and Fournier removed TriCor® capsules from the NDDF, there was no longer a brand reference drug for Teva's fenofibrate capsules. Abbott's and Fournier's only purpose in removing the capsule code from the NDDF was to foreclose generic competition from Teva and other generic manufacturers in the fenofibrate product market. Had the capsule code not been removed from the NDDF (even if Abbott had ceased producing or marketing the products), there would still have been an NDDF reference for which Teva's generic capsules could have been substituted. Without the TriCor® capsule code as a reference, however, and without the continuation of Abbott's capsules in the marketplace, there was no longer a market for generic fenofibrate capsule products.").

confirmed at the hearing on this matter that they are not asserting a separate cause of action based on these FDA communications. Rather, Plaintiffs' allegations regarding the Hoechst Defendants' FDA communications are merely evidence in support of the Plaintiffs' state law claims.") Accordingly, the First Amendment cannot serve as a basis to shield consideration of Defendants' withdrawal of the NDDF code and the anticompetitive consequences of that action as part of an overall scheme.

In sum, End-Payor Plaintiffs have sufficiently alleged facts demonstrating that Defendants destroyed the market for their initial fenofibrate products on the brink of generic competition and thereby maintained an unlawfully monopoly in the market for fenofibrate products. Defendants' contentions to the contrary simply ignore the actual allegations in the End-Payor Complaint and fail to construe those allegations in the light most favorable to End-Payor Plaintiffs.

B. Defendants Engaged In Inequitable Conduct Before The PTO And Engaged In Sham Litigation To Unlawfully Maintain A Monopoly.

End-Payor Plaintiffs have incorporated by reference Teva's counterclaims alleging that Fournier committed inequitable conduct before the PTO in obtaining relevant patents and that Abbott and Fournier filed sham patent infringement litigations in furtherance of their conspiracy to monopolize the market for fenofibrate. *See* ¶¶ 81-85. Rather than burden the Court with the same arguments other plaintiffs will make in support of these allegations, End-Payor Plaintiffs will defer to the briefing by other plaintiffs. *See* Teva Br. Section V., Pacificare Br. Section III.E., Direct Purchaser Plaintiffs' Br. Section IV.H. That said, Defendants' blanket assertion that no plaintiff has pleaded antitrust injury (Defs. Br. at 26-29) is plainly wrong and requires a brief response.

The antitrust laws were "enacted to assure customers the benefits of price competition." *Associated Gen. Contractors v. California State Council of Carpenters*, 459 U.S. 519, 538 (1983). *See also Reiter v. Sonotone*, 442 U.S. 330 (1979) (consumers who pay higher prices as a result of antitrust violations have standing to bring claims under the Clayton Act). As discussed above, the End-Payor Complaint details how the introduction of generic competition benefits end-payors, who can pay less than brand-name prices for drugs that are the therapeutic equivalent of brand-name products. *See* pp. 6-7, *supra*. *See also, e.g.*, ¶ 31 (per 1998 Congressional Budget Office study, first generic entrant typically prices product at 60 to 70% of the brand price, and after entry by multiple generic competitors the price can stabilize at 20 to 30% of the brand price); ¶ 97 ("As a result of Defendants' anti-competitive conduct, Plaintiffs and the Class have been financially injured . . [and] have paid and reimbursed supra-competitive and artificially high prices for TriCor® products.").

The End-Payor Complaint alleges, at its core, that Defendants have engaged – and continue to engage – in anticompetitive conduct that prevents generic competition in the market for prescription fenofibrate products and causes end-payors of TriCor to pay supra-competitive prices for the drug. That injury is a paradigmatic "antitrust injury," *i.e.*, injury of the type contemplated by the antitrust laws. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (antitrust injury "should reflect the anticompetitive effect either of the violation or of the anticompetitive acts made possible by the violation. It should, in short, be the type of loss that the claimed violations . . . would be likely to cause.") (internal quotation marks and citation omitted). *See also* 2 Julian O. von Kalinowski, et al, *Antitrust Laws and Trade Regulation* § 27.01[1] (2d ed.2005), antitrust injury consists of: "(1) a defendant's anti-competitive conduct, which resulted in measurable injuries to plaintiffs, and (2) injuries

stemming from the competition-reducing aspects or effects of the defendant's behavior, and of the type that the antitrust laws were designed to prevent".

Warfarin II, 214 F.3d 395, is particularly instructive on what constitutes antitrust injury. There, the Third Circuit reinstated claims of end-payors of the brand-name drug Coumadin that had been dismissed by the District Court on the defendant's pleadings motion. The end-payor plaintiffs sought injunctive relief against DuPont Pharmaceuticals Company, Coumadin's manufacturer. As is the case here, DuPont was accused of engaging in anticompetitive conduct that prevented competition in the Coumadin market and caused Coumadin users to pay supra-competitive prices for the drug. *See id.* at 396-97, 400. Holding that the end-payor plaintiffs had standing to pursue their claims, the Court stated that "the excess amount paid by Coumadin users not only is inextricably intertwined with the injury DuPont aimed to inflict, the overcharge was the aim of DuPont's preclusive conduct. *It is difficult to imagine a more formidable demonstration of antitrust injury.*" *Id.* at 401 (emphasis added; internal quotes omitted). *See also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 911 (6th Cir. 2003) ("[H]ere there is no question that the alleged injury – paying higher prices for a product due to a lack of competition in the market – is the type of injury that can, and the plaintiffs have alleged did, flow from" defendants unlawful conduct).

Defendants' wrongful acquisition and listing of patents, and its strategic utilization of Hatch-Waxman litigation, which in combination have the purpose and effect of delaying the launch of competitive generic products until after Defendants are able to launch a new formulation of their TriCor product, are key tactics in Defendants' overall anticompetitive scheme. Even without Fournier's admission that Defendants' aim is to REDACTED

REDACTED the End-Payor Complaint describes a similarly

"formidable demonstration of antitrust injury" as a direct result of that scheme. Thus, Defendants' motion is not well-taken and should be denied.

C. End-Payor Plaintiffs' State Law Claims Should Be Sustained.

Defendants contend that End-Payor Plaintiffs' state law antitrust claims (Count II) should be dismissed because these states generally follow federal precedents. Defs. Br. at 38. With certain exceptions, End-Payor Plaintiffs agree that federal antitrust standards are equally applicable to the states.[13] For the reasons addressed above, however, End-Payor Plaintiffs have properly alleged a violation of § 2 of the Sherman Act that is also sufficient to satisfy the requirements of the state statutes asserted in Court II. *See, e.g., United States v. Microsoft Corp.*, 87 F. Supp. 2d 30, 54 n. 7 (D.D.C. 2000), *aff'd in part and reversed in part on other grounds by*, 253 F.3d 43 (D.C. Cir. 2001). "The facts proving that Microsoft unlawfully maintained its monopoly power in violation of § 2 of the Sherman Act are sufficient to meet analogous elements of causes of action arising under the laws of each plaintiff state." (footnote omitted).

Defendants *further* seek dismissal of claims under consumer protection act statutes (Counts IV and V) because End-Payor Plaintiffs have purportedly failed to allege deception. Defs. Br. at 38-39. However, End-Payor Plaintiffs have alleged that, in support of their anticompetitive strategy, Defendants' procured fraudulent patents and listed them in the Orange Book. ¶¶ 81-85, 119 (incorporating Teva's counterclaim). Moreover, Count IV of the End-

---

[13] One of those exceptions is that the state claims included in Count II are under statutes that do not adhere to the federal "direct purchaser" rule articulated in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1978). *See, e.g., Bunker's Glass Co. v. Pilkington PLC*, 75 P.3d 99 (Ariz. 2003) (rejecting application of *Illinois Brick* under state law); *Mack v. Bristol-Myers Squibb Co.*, 673 So.2d 100 (Fla. Dist. Ct. App. 1996) (same); *Comes v. Microsoft Corp.*, 646 N.W.2d 440 (Iowa 2002) (same); *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 436 Mass. 53, 762 N.E.2d 303 (2002) (same); *Arthur v. Microsoft Corp.*, 267 Neb. 586, 676 N.W.2d 29 (2004) (same).

Payor Complaint alleges violation of the Delaware Consumer Fraud Act, 6 Del. C. §2513 ("DCFA"), a fact Defendants conveniently ignore. Under Delaware law, Plaintiffs easily satisfy their pleading burden because the DCFA does not require that Plaintiffs plead or prove individual reliance on Defendants' inequitable conduct in purchasing TriCor. *See Stephenson v. Capano Dev., Inc.* 462 A.2d 1069, 1074 (Del. 1983) ("[a]n unlawful practice under section 2513(a), however, is committed regardless of actual reliance by the plaintiff"); *S&R Assocs.* v. *Shell Oil Co.*, 725 A.2d 431, 440 (Del. Super. Ct. 1998) ("While a fraud action at common law requires the plaintiff to prove reliance, there is no corresponding reliance requirement in 6 Del. C. § 2513. The Plaintiff need only prove that the Defendant intentionally concealed material facts with the intent that others would rely upon such concealment. *Id.*"). *See also Warfarin III*, 212 F.R.D. at 248 (plaintiffs' DCFA claims "do not rely on the conduct or reliance of individual consumers or [third-party payors]").

In any event, statutes in many states do not even require "deception." *See, e.g., In re New Motor Vehicles Can. Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 186-87, 195-96, 205-06 (D. Me. 2005) (denying motion to dismiss claims that sound in antitrust to the extent that state statutes that require only "unfair methods of competition," "unconscionable business practice" or "unfair trade practices"). Thus, Defendants' attack on Count V fails as well.

V. CONCLUSION

For all the foregoing reasons, Defendants' motion to dismiss should be denied.

Dated: December 2, 2005

CHIMICLES & TIKELLIS LLP

Pamela S. Tikellis (#2172)
Robert J. Kriner, Jr. (#2546)
A. Zachary Naylor (#4439)
Robert R. Davis (#4536)
P.O. Box 1035
One Rodney Square
Wilmington, DE 19899
Tel: 302-656-2500
Fax: 302-656-9053
Liaison Counsel for End-Payor Plaintiffs

LABATON SUCHAROW & RUDOFF LLP
Bernard Persky
Christopher J. McDonald
Kellie C. Safar
100 Park Avenue
New York, NY 10001

SPECTOR, ROSEMAN & KODROFF, P.C.
Jeffrey L. Kodroff
Theodore M. Lieverman
Simon B. Paris
1818 Market Street, Suite 2500
Philadelphia, PA 19103

MILLER FAUCHER and CAFFERTY LLP
Bryan L. Clobes
William R. Kane
One Logan Square
18 & Cherry Streets, Suite 1700
Philadelphia, PA 19103
-and-
Patrick E. Cafferty
101 N. Main Street, Suite 450
Ann Arbor, MI 48101
-and-
Marvin A. Miller
Jennifer W. Sprengel
30 N. LaSalle St. Suite 3200
Chicago, IL 60602

HAGENS BERMAN SOBOL SHAPIRO LLP
Thomas M. Sobol
David S. Nalvin
Gregory H. Matthews
One Main Street, 4th Floor
Cambridge, MA 02142
-and-
Steve W. Berman
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101

Interim Co-Lead Counsel for End-Payor Plaintiffs